IDEC 131: adverse reactions

Various toxicities

In patients with relapsing-remitting multiple sclerosis

Study Details

Purpose

This study investigated the tolerability of IDEC 131 [*αCD154*] in patients with relapsing-remitting multiple sclerosis.

Details

Design:	sequential
Control:	baseline comparison, drug dosage comparison
Phase:	Phase I
Concomitant Medication:	None

Subjects

Type	No.	Sex	Age
patients	12		not stated

Treatments

IDEC 131 (1 mg/kg)

Drug/Treatment	Dose	Route	Frequency	Duration
IDEC 131	1 mg/kg/dose	not stated	2/week	4 doses

IDEC 131 (5 mg/kg)

Drug/Treatment	Dose	Route	Frequency	Duration
IDEC 131	5 mg/kg/dose	not stated	2/week	4 doses

IDEC 131 (10 mg/kg)

Drug/Treatment	Dose	Route	Frequency	Duration
IDEC 131	10 mg/kg/dose	not stated	2/week	4 doses

IDEC 131 (15 mg/kg)

Drug/Treatment	Dose	Route	Frequency	Duration
IDEC 131	15 mg/kg/dose	not stated	2/week	4 doses

Results

Multiple doses of IDEC 131 at 1 mg/kg, 5 mg/kg, 10 mg/kg and 15 mg/kg were found to be safe in all patients. Fifteen adverse events were reported of mild to moderate severity which were considered to be possibly treatment-related. IDEC 131 was not associated with any evidence of toxicity as assessed by the Expanded Disability Status Scale, laboratory parameters, relapse rate and other clinical indications.

Adis Assessment

Study Messages

- IDEC 131 at a dosage of 1 mg/kg, 5 mg/kg, 10 mg/kg or 15 mg/kg is generally well tolerated in patients with relapsing-remitting multiple sclerosis.

Adis Evaluation

Trial Design:

Clinical Relevance:	Provides new evidence of clinical benefit and has major implications for a patient population.

Reference

Fadul CE, Ryan KA, Noelle RJ, Wishart HA, Saykin AJ, et al. Therapeutic intervention of multiple sclerosis with a CD40 ligand antagonist: a phase I clinical trial. Neurology 60 (Suppl. 1): 84, 11 Mar 2003
Lebanon, New Hampshire, USA

Fax Message

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Date	24 March 2005
Number of pages	(including this one) 7

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